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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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12/30/2003

Yanan Zhang

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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/751,327	Applicant(s) ZHANG ET AL.	
	Examiner Karen E. Toth	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 21-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-20, 34-36 and 38-43 is/are rejected.
- 7) ☒ Claim(s) 12, 13 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The oath presently states "my duty to disclose information, which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations §1.56(a)." This declaration should state --the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56.--

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3735

4. Claims 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation “adjusting the nominal output current of the sensor a second time based on data in the calibration array.” It is not clear whether the calibration array data being used for this adjustment is the initial data or the adjusted data, since neither has been specified. For the purposes of examination, the claim will be treated as though the adjusted calibration array data is what is used for the second output adjustment.

Claim 20 recites the limitation "the twice adjusted sensor parameter" in line 1. There is insufficient antecedent basis for this limitation in the claim, as none of the claimed parameters in claim 1 have been adjusted twice, nor have any been identified as a “sensor parameter”.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-9, rejected under 35 U.S.C. 102(e) as being anticipated by Iyengar (US Patent Application Publication 2005/0109637).

Regarding claim 1, Iyengar discloses a method of adjusting a sensor's calibrating curve comprising compiling a calibration array of data values related to the sensor and generating a calibration curve (λ), adjusting a nominal sensor output current (I_{measured} ; paragraph [0054]) based on the calibration array, and adjusting the calibration curve based on the adjusted sensor output (paragraphs [0104], [0171]-[0177], [0182], [0186]).

Regarding claims 2 and 4, since Applicant has not defined time periods for the terms "historical" and "recent", they may be interpreted based on their broadest reasonable definitions. As such, the data Iyengar uses to generate the calibration curve may be considered either historical or recent, depending on a user's contextual information.

Regarding claims 3 and 7, Iyengar further discloses the data being blood glucose readings (paragraphs [0002], [0051], [0080]).

Regarding claim 5, Iyengar further discloses the data coming from electrodes (elements 100 and 105; paragraph [0070]).

Regarding claim 6, Iyengar further discloses the electrode readings comprising glucose and oxygen electrode readings (paragraphs [0079]-[0080]).

Regarding claim 8, Iyengar further discloses the nominal output current being a glucose current (paragraphs [0057]-[0059]).

Regarding claim 9, Iyengar further discloses the nominal current adjustment being based on a shift of measured data points (paragraph [0077]).

Regarding claim 11, Iyengar further discloses using linear regression on the calibration data (paragraph [0073]).

Regarding claims 34 and 36, Iyengar further discloses generating a calibration curve based on a priori empirical values (paragraph [0169]), compiling a plurality of data values from the sensor (I_{measured}), compiling independent historical values measured by the sensor (paragraph [0169] – proportionality constant λ), and using the historical values to correlate between the data values and the calibration curve (paragraphs [0171]-[0173]).

Regarding claims 35 and 38, Iyengar further discloses the sensor being a glucose sensor and the historical parameters being metered blood glucose values (paragraphs [0002], [0051], [0080]).

Regarding claims 39 and 40, Iyengar further discloses adjusting a nominal glucose output current of the sensor (paragraphs [0057]-[0059]).

Regarding claim 41, Iyengar further discloses the current adjustment being based on a shift of the sensor data values with respect to the metered values (paragraph [0077]).

Regarding claim 42, Iyengar further discloses the reconciling comprising linear regression of the data values (paragraph [0073]).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iyengar in view of Monfre (US Patent Application Publication 2005/0203358).

Iyengar discloses all the elements of the claimed invention, as disclosed above, except for the shift being a mean shift. Monfre teaches a calibration method for use when measuring glucose concentration comprising performing a mean shift of the data (paragraph [0167]), as is well known in the art when performing calibration. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed a mean shift of the data, as taught by Monfre, when using Iyengar, since it is well known in the art to shift by a mean shift when calibrating a system.

9. Claims 14, 15, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyengar in view of Lambert (US Patent Application Publication 2004/0019283).

Regarding claims 14 and 43, Iyengar discloses all the elements of the claimed invention, as disclosed above, except for adjusting the sensor output calibration curve in a piecewise linear fashion. Lambert teaches adjusting a calibration curve in a piecewise linear fashion (paragraph [0260]), as is well known in the art when choosing a method of calibration. It would have been obvious to one of ordinary skill in the art at the time the

invention was made to have chosen to perform piecewise linear calibration, as taught by Lambert, with the system of Iyengar, since it is well known in the art as a method of calibration.

Regarding claim 15, Applicant has not disclosed the number of pieces in the piecewise linear regression being for a specific reason or solving a stated problem. As such, the exact number of pieces used in the piecewise linear regression would be a mere matter of design choice for one skilled in the art.

10. Claims 16-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyengar in view of Berner (US Patent Application Publication 2003/0153820).

Regarding claims 16 and 20, Iyengar discloses all the elements of the claimed invention, as described above, except for the nominal output current of the sensor being adjusted a second time. Berner teaches a method of calibrating a sensor comprising repeating the calibration steps iteratively (paragraphs [0069]-[0070], [0193]), in order to obtain more information from the data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Iyengar and adjusted the nominal sensor output current a second time, as taught by Berner, in order to obtain more information from the collected data.

Regarding claim 17, Iyengar further discloses the nominal output current being a glucose current (paragraphs [0057]-[0059]).

Regarding claim 18, Iyengar further discloses the nominal current adjustment being based on a shift of measured data points (paragraph [0077]).

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Iyengar in view of Berner, as applied to claims 16-18 above, and further in view of Monfre.

Iyengar in view of Berner discloses all the elements of the claimed invention, as disclosed above, except for the shift being a mean shift. Monfre teaches a calibration method for use when measuring glucose concentration comprising performing a mean shift of the data (paragraph [0167]), as is well known in the art when performing calibration. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed a mean shift of the data, as taught by Monfre, when following Iyengar in view of Berner, since it is well known in the art to shift by a mean shift when calibrating a system.

Allowable Subject Matter

12. Claims 12, 13, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the inventions of claims 12 and 13, including, *inter-alia*, adjusting a sensor calibration curve by compiling an array of data, generating a calibration curve, adjusting a nominal output current, and adjusting the calibration curve based on the nominal output current by performing linear regression on the array of data, where the linear regression determines a first calibration point.

The prior art of record fails to anticipate or make obvious the invention of claim 37, including, *inter-alia*, adjusting a sensor calibration curve by compiling an array of data, generating a calibration curve based on a priori empirical values representing a sensor having a plurality of phases, adjusting a nominal output current, and adjusting the calibration curve based on the nominal output current, compiling a plurality of data values from the sensor, combining independent historical values, using the historical values to reconcile differences between the sensor data values and the calibration curve.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publications 2004/0220460 and 2007/0060811 to Roberts, which disclose similar inventions.

US Patent 6275717 to Gross, which discloses similar inventions.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 3735

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser/
Primary Examiner, Art Unit 3735

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